ANI Pharmaceuticals Inc.

URGENT: DRUG PRODUCT RECALL

DATE: 02/15/2022

Dear Customer:

This is to inform you of a product recall involving the following Par Pharmaceutical products (prior ANDA holder) due to potential cross-contamination at their contract manufacturer (Ultra Tab Laboratories Inc.).

Product & NDC Number	Lot Number
Alprazolam Tablets, USP 0.25 mg (NDC Number's) 67253-900-10, 100 TABLET in 1 BOTTLE, 67253-900-50, 500 TABLET in 1 BOTTLE, 67253-900-11, 1000 TABLET in 1 BOTTLE	19C003A, 03/2022, 19C004B, 03/2022, 19C048C, 03/2022, 19G002A, 07/2022,
Alprazolam Tablets, USP 0.5 mg (NDC Number's) 67253-901-10, 100 TABLET in 1 BOTTLE, 67253-901-50, 500 TABLET in 1 BOTTLE, 67253-901-11, 1000 TABLET in 1 BOTTLE	19A087B, 02/2022,19A088B, 02/2022, 19A089B, 02/2022,19A090B, 02/2022, 19B020C, 02/2022,19B021C, 02/2022, 19B027C, 02/2022,19B028C, 02/2022, 19B029A, 02/2022,19E056C, 05/2022, 19A086B, 02/2022,19A091B, 02/2022, 19B019B, 02/2022,19D021A, 04/2022, 19E057C, 05/2022,19E059C, 06/2022, 19G072C, 07/2022,
Alprazolam Tablets, USP 1.0 mg (NDC Number's) 67253-902-10, 100 TABLET in 1 BOTTLE, 67253-902-50, 500 TABLET in 1 BOTTLE, 67253-902-11, 1000 TABLET in 1 BOTTLE	19A102B, 02/2022, 19B081A, 02/2022, 19B082C, 03/2022, 19B083C, 03/2022, 19D067B, 04/2022, 19D068B, 04/2022, 19D069C, 05/2022, 19D070C, 05/2022, 19E088A, 05/2022, 19E089A, 05/2022 19F045C, 06/2022, 19F046C, 06/2022
Alprazolam Tablets, USP 2.0 mg (NDC Number's) 67253-903-50, 500 TABLET in 1 BOTTLE, 67253-903-10, 100 TABLET in 1 BOTTLE	19C002A, 03/2022, 19C100B, 04/2022, 19E001B, 05/2022, 19E002B, 05/2022, 19E012A, 05/2022,19E013A, 05/2022,
Pyrazinamide Tablets, USP 500mg (NDC Number's) 67253-660-10, 100 TABLET in 1 BOTTLE	19B064A, 03/2022

See enclosed product labeling for the drug products for ease in identifying the product. This drug product was manufactured by Ultra Tab Laboratories, Inc. (Hightstown, N.Y.) for Par Pharmaceuticals, Inc. This recall has been initiated due to potential cross-contamination with other drug substances during the manufacturing process. ANI Pharmaceuticals is the current application holder for the affected drug product. This recall does not involve product manufactured or distributed by ANI Pharmaceuticals or its subsidiary Novitium Pharma.

The affected products were distributed within the following dates:

Alprazolam Tablets, USP 02/21/2019 to 10/03/2019

Pyrazinamide Tablets, USP 04/04/2019 to 10/01/2019

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

In our best efforts to coordinate the prompt and secure return of the affected product, ANI Pharmaceuticals has contracted with Sedgwick Inc. to provide support for this recall. Instruction for reimbursement and the return of goods to Sedgwick is provided on the Recall Response Form (enclosed).

Sedgwick Return Management Services
2670 Executive Dr
Indianapolis, IN 46241
RE: Event #: 6613

ANI Pharmaceuticals kindly requests that you provide Sedgwick with the quantities of your inventory on hand, along with the address and contact person at each location, within the next 60 days. Enclosed you will find a form on which to record your current inventory of recalled material and the number of customers directly contacted. Please complete and return the form via fax or email (even if you have no inventory to return).

This recall is being carried out to the retail level. Your assistance is appreciated and necessary to prevent potential impact to any customer.

If you have any questions, please reach out to Sedgwick at 888-266-7969 or anipharma6613@sedgwick.com

This recall is being made with the knowledge of the Food and Drug Administration.

Enclosure(s)

- **Recall Response Form**
- **Drug Product Labeling**

Pyrazinamide Tablets

Product & NDC Number	Lot Number	Quantity to Return
Pyrazinamide Tablets, USP 500mg		
67253-660-10, 100 TABLET in 1 BOTTLE		

Please complete for Pyrazinamide tablets and email or fax to: anipharma6613@sedgwick.com or FAX: 888-208-4588

Customer Information:

Contact Name: _____

Contact Phone Number: _____

Address: _____ City, State & Zip: _____

Wholesaler Name: _____ Wholesaler City & State: _____

DEA #_____ Debit/Reference Number: _____

(Please check the appropriate box)

☐ We have read and understand the recall instructions provided in the (date) letter

☐ We have product from one/some of the recalled lots and will be making a return. (Please provide information below.)

☐ We have NONE of the recalled lots in stock.

☐ We have identified and notified our customers that were shipped or may have been shipped this product.

Signature: _____ **Date:** _____

Alprazolam Tablets

Product & NDC Number	Lot Number	Quantity to Return
Alprazolam Tablets, USP 0.25 mg		
67253-900-10, 100 TABLET in 1 BOTTLE		
67253-900-50, 500 TABLET in 1 BOTTLE		
67253-900-11, 1000 TABLET in 1 BOTTLE		
Alprazolam Tablets, USP 0.5 mg		
67253-901-10, 100 TABLET in 1 BOTTLE,		
67253-901-50, 500 TABLET in 1 BOTTLE		
67253-901-11, 1000 TABLET in 1 BOTTLE		
Alprazolam Tablets, USP 1.0 mg		
67253-902-10, 100 TABLET in 1 BOTTLE,		
67253-902-50, 500 TABLET in 1 BOTTLE		
67253-902-11, 1000 TABLET in 1 BOTTLE		
Alprazolam Tablets, USP 2.0 mg		
67253-903-50, 500 TABLET in 1 BOTTLE		
67253-903-10, 100 TABLET in 1 BOTTLE		

Please complete for Alprazolam Tablets and email or fax to: anipharma6613@sedgwick.com or FAX: 888-208-4588
Customer Information:

Contact Name: _____

Contact Phone Number: _____

Address: _____ City, State & Zip: _____

Wholesaler Name: _____ Wholesaler City & State: _____

DEA #_____ Debit/Reference Number: _____

(Please check the appropriate box)

☐ We have read and understand the recall instructions provided in the 2/15/22 letter

☐ We have product from one/some of the recalled lots and will be making a return. (Please provide information in table above.)

☐ We have NONE of the recalled lots in stock.

☐ We have identified and notified our customers that were shipped or may have been shipped this product.

Signature: _____ **Date:** _____